Paper No. 41

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte KEITH BAKER and ARTHUR J. COURY

Appeal No. 2003-1736
Application No. 09/123,137

HEARD: January 8, 2004

Before SCHEINER, MILLS and GRIMES, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. §134 from the examiner's final rejection of claims 1, 9-25 and 27-30, which are all of the claims pending in this application.

Claim 1 is illustrative of the claims on appeal and reads as set forth below:

1. A composition for the local alleviation of a medical condition caused by inflammation or unwanted tissue proliferation at a site, the composition comprising

an effective amount of one or more active oxygen inhibitor compounds which destroy or prevent the formation of active oxygen species in a polymer solution or hydrogel, wherein the polymer solution or hydrogel is administered to the site in fluent form and forms a conforming barrier by ionic crosslinking, chemical redox reaction,

photopolymerization, or physical gelation at the site of administration, and

wherein the barrier persists at the site for days to weeks.

The references are relied upon by the examiner are:

Hettinger	4,371,519	Feb. 1, 1983
WO 93/17669	PCT Application	Sept. 16,1993

Sawhney et al. (Sawhney 1), "Optimization of photopolymerized bioerodible hydrogel properties for adhesion prevention," J. Biomed. Mats. Res., Vol. 28, pp. 831-838 (1994)

Sawhney et al. (Sawhney 2), "Interfacial photopolymerization of poly(ethylene glycol)-based hydrogels upon alginate-poly (L-lysine) microcapsules for enhanced biocompatibility," Biomaterials, Vol. 14, pp. 1008-1016 (1993)

Grounds of Rejection

Claims 1, 9-25 and 27-30 stand rejected for obviousness-type double patenting over claims 1-42 of U.S. Patent No. 5,785,993.

Claims 1, 9-25 and 27-30 stand rejected under 35 U.S.C. § 103 over Sawhney 1, Hettinger by themselves or together, in further combination with applicants' statement of prior art and optionally in further combination with WO 93/17669 and Sawhney 2.

The rejection for obviousness-type double patenting is affirmed. The rejection of the claims for obviousness is reversed.

DISCUSSION

In reaching our decision in this appeal, we have given consideration to the appellants' specification and claims, to the applied references, and to the respective positions articulated by the appellants and the examiner.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the noted rejections, we make reference to the examiner's Answer for the examiner's reasoning in support of the rejection, and to the appellants' Brief for the appellants' arguments thereagainst. As a consequence of our review, we make the determinations which follow.

Background

The composition of claim 1 is a composition for the local alleviation of a medical condition caused by inflammation or unwanted tissue proliferation at a site, the composition comprising an effective amount of one or more active oxygen inhibitor compounds which destroy or prevent the formation of active oxygen species in a polymer solution or hydrogel, wherein the polymer solution or hydrogel is administered to the site in fluent form and forms a conforming barrier by ionic crosslinking, chemical redox reaction, photopolymerization, or physical gelation at the site of administration, and wherein the barrier persists at the site for days to weeks.

According to the invention superoxide dismutase (SOD) and other oxygen inhibitors are directly applied in combination with a barrier material at local sites of tissue injury to prevent or decrease formation of adhesions and undesirable proliferation of cells. Specification, page 6. The specification describes that compositions such as those claimed are particularly useful in the treatment of secondary adhesions. Specification, pages 27-29. According to the specification,

page 5, the formation of primary adhesions depends on the persistence of fibrin bridges between the disjoint parts, which are subsequently colonized by other cells and develop into permanent vascularized tissue. Secondary adhesions may be the result of the normal healing process which involves the mobilization of several cell types and the formation of new collagen and typically has initial stages lasting for up to two weeks followed by several months of maturation. Id.

Obviousness-type Double Patenting

Claims 1, 9-25 and 27-30 stand rejected for obviousness-type double patenting over claims 1-42 of U.S. Patent No. 5,785,993.

The examiner argues that although the conflicting claims are not identical they are not patentably distinct from one another because the instant generic terminology encompasses the fluid composition and the specific oxygen inhibitors in the claims of the patent.

Appellants have indicated in their brief the willingness to file a terminal disclaimer once the claims have been determined to be otherwise allowable. Brief, page 15. In as much as no terminal disclaimer has been made of record to date, the rejection for obviousness-type double patenting is affirmed.

35 U.S.C. § 103

Claims 1, 9-25 and 27-30 stand rejected under 35 U.S.C. § 103 over Sawhney 1, Hettinger by themselves or together, in further combination with applicants' statement of

prior art and optionally in further combination with WO 93/17669 and Sawhney 2.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). It is well-established that the conclusion that the claimed subject matter is prima facie obvious must be supported by evidence, as shown by some objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led that individual to combine the relevant teachings of the references to arrive at the claimed invention. See In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

It is the examiner's position that Sawhney 1 teaches that bioerodible hydrogels could be photopolymerized in vivo for the prevention of tissue adhesions but does not teach the addition of the inhibitors of reactive oxygen species. Answer, page 6.

Hettinger is relied on by the examiner for its teaching that the polymerization of acrylamides at a tumor site reduces the influx of oxygen to the site, but does not teach the addition of inhibitors of reactive oxygen species to the acryamide. Id.

To make up for these deficiencies in the prior art, the examiner finds “Applicants disclose in the specification of the art well-known effectiveness of the claimed compounds against tissue adhesions (see pages 3-5).” Answer, page 6. Sawhney 2 is relied on for the disclosure of the use of hydrogels for adhesion prevention. Answer, page 7.

The examiner concludes (Id., page 6):

> It would have been obvious to an artisan to combine two different agents well-known in the art for use against the same condition with the expectation of obtaining at least an additive effect. ... An artisan would be further motivated to use the combination of the photopolymerizable hydrogels and the reactive oxygen species inhibitors in view of the disclosure of WO [93/17669] which teaches that by using the polymerizable gels one can also encapsulate various macromolecules such as enzymes (SOD is an enzyme) and drugs affecting reproductive organs (instant claim 31, endometriosis) for sustained drug delivery. It should be pointed out that WO uses the gels for the same purpose (see the abstract and page 18). The use of microcapsules encapsulating the inhibitors of reactive oxygen species, within the hydrogel would have been obvious to an artisan since such combination of microcapsules/hydrogels have enhanced biocompatibility as taught by Sawhney [2] 1993 (note the abstract and 1012) and also since it provides double protection to the encapsulated inhibitors.

The appellants argue that the examiner has failed to establish a prima facie case of obviousness and that nothing in the cited references would lead one of ordinary skill in the art to combine the gels of the cited references with the compounds described in the appellants' specification, with any expectation of success. Brief, page 13. We agree. The appellants argue that the prior art referenced in the specification discloses the systemic administration of agents which destroy oxygen species using an intravenous bolus before surgery, however the effectiveness of the agents was limited by their rapid elimination from the blood stream. Brief, page 11. In contrast, the appellants' claims require that the barrier containing an active oxygen inhibitor persist at the site for days to weeks. With respect to WO 93/17669 which teaches the incorporation of drugs or enzymes in hydrogels, appellants argue that “WO 93/17669 does not teach the selection of active oxygen inhibitors from among the many different

types of enzymes." Reply Brief, page 4.

In the present case, the examiner has failed to indicate the specific understanding or principle within the knowledge of a skilled artisan, explicit or implicit, that would have motivated one with no knowledge of appellants' invention to make the combination in the manner claimed. In re Rouffet, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457 (Fed. Cir. 1998). In re Kotzab, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000).

What is missing from the examiner's analysis is a sufficient reason, suggestion or motivation to combine the cited references. More particularly, the examiner has not indicated why one of ordinary skill in the art would have been motivated to select or include active oxygen inhibitors, such as SOD, in the prior art hydrogels. While it is clear from the record that both SOD and hydrogels were known in the art, we do not find the examiner has established with proper evidence, the motivation to incorporate an active oxygen inhibitor in a hydrogel.

We do not agree with the examiner that the mention of the incorporation of enzymes in a hydrogel (WO 93/17669) would have suggested the incorporation of SOD in a hydrogel. It is well settled that the fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a prima facie case of obviousness. In re Baird, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994) ("The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious."); In re Jones, 958 F.2d 347,

350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992) (Federal Circuit has "decline[d] to extract from Merck [& Co. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir. 1989)] the rule that... regardless of how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it."). See also In re Deuel, 51 F.3d 1552, 1559, 34 USPQ2d 1210, 1215 (Fed. Cir. 1995). Thus, without more, the disclosure of the incorporation of enzymes in a hydrogel as set forth in WO 93/17669 does not provide a sufficient reason, suggestion or motivation to incorporate specific active oxygen inhibitors in a hydrogel.

The burden is on the examiner to set forth a prima facie case of obviousness. See In re Alton, 76 F.3d 1168, 1175, 37 USPQ2d 1578, 1581 (Fed. Cir. 1996). With respect to an obviousness rejection based on a combination of references, as the court has stated, "virtually all [inventions] are combinations of old elements." Environmental Designs, Ltd. V. Union Oil Co., 713 693, 698, 218 USPQ 865, 870 (Fed. Cir. 1983); see also Richdel, Inc. v. Sunspool Corp., 714 F.2d 1573, 1579-80, 219 U.S.P.Q. (BNA) 8, 12 (Fed. Cir. 1983) ("Most, if not all, inventions are combinations and mostly of old elements."). Therefore, an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. The United States Court of Appeals for the Federal Circuit, our reviewing court, however, has stated that "the best defense against hindsight-based obviousness analysis is the rigorous application of the requirement for a showing of a teaching or motivation to combine the

prior art references." Ecolochem, Inc. v. Southern California Edison Co., 227 F.3d 1361, 1371, 56 USPQ2d 1065, 1073 (Fed. Cir. 2000).

In this situation, the examiner's rejection fails to show that one of ordinary skill in the art would have been motivated to incorporate an active oxygen species in a hydrogel, as claimed. In addition, the prior art noted in the specification discloses that the efficacy of SOD use for the treatment of ischemic/reperfusion events and pelvic adhesions has been limited by its rapid elimination from the blood stream. Specification, page 4. The examiner has not provided sufficient evidence to indicate why one of ordinary skill in the art would have been motivated to incorporate an active oxygen inhibitor which is known to be rapidly eliminated from the blood stream into a hydrogel, as claimed. Nor has the examiner provided evidence as to why one of ordinary skill in the art in view of the prior art disclosure of systemic administration of oxygen inhibitors such as SOD, would have been motivated to apply such compositions topically or would have had an expectation of success that the composition would continue to deliver the active oxygen inhibitor, normally rapidly eliminated from the blood stream, at a site for days to weeks.

We do not reach appellants' argument or evidence of unexpected results, as we do not find the examiner has established a prima facie case of obviousness. The rejection of the claims for obviousness is reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

CONCLUSION

The rejection of claims 1, 9-25 and 27-30 for obviousness-type double patenting over claims 1-42 of U.S. Patent No. 5,785,993 is affirmed. The rejection of claims 1, 9-25 and 27-30 under 35 U.S.C. § 103 over Sawhney 1, Hettinger by themselves or together, in further combination with applicants' statement of prior art and optionally in further combination with WO 93/17669 and Sawhney 2 is reversed.

AFFIRMED

TONI R. SCHEINER Administrative Patent Judge	)
DEMETRA J. MILLS Administrative Patent Judge	) BOARD OF PATENT) APPEALS AND) INTERFERENCES
ERIC GRIMES Administrative Patent Judge	)

Appeal No. 2003-1736
Application No. 09/123,137

HOLLAND AND KNIGHT LLP
Suite 2000, One Atlantic Center
1201 West Peachtree Street, N.E.
Atlanta, GA 30309-3400